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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/065,279

09/30/2002

Jeffrey C. Leung

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ANGIOTECH

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EXAMINER

NGUYEN, TUAN VAN

ART UNIT

PAPER NUMBER

3731

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/065,279	<b>Applicant(s)</b> LEUNG ET AL.	
	<b>Examiner</b> TUAN V. NGUYEN	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on March 22, 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-58, 60 and 63-140 is/are pending in the application.
- 4a) Of the above claim(s) 37-57 and 63-101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36, 58, 60 and 102-140 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 November 2003 and 16 December 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Claims 1-58, 60 and 63-140 are pending in this present application. In previous Office action claims 1-36, 58, 60 and 102-140 were examined and rejected and claims 37-57 and 63-101 were previously withdrawn due to restriction requirement.
2. This Office action is in response to the RCE filed on 12/7/09.

#### ***Continued Examination Under 37 CFR 1.114***

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after the final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/7/09 has been entered.

#### ***Response to Amendment***

4. Applicant's arguments filed on 12/7/09 with respect to the new limitation in independent claims 1, 10, 19, 28, 58 and 60 have been fully considered but they are moot in view of new ground of rejection.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claims 1-3, 5-9, 10, 12, 14-21, 23-30, 32-36, 58, 60 and 102-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke (U.S. 5,931,855) in view of Morency et al. (US 2003/0149447).**

8. Referring to **claims 1-3**, Buncke discloses (see Figures 2 and 13) a barbed suture 84 having a elongate body having a longitudinal axis and barbs positioned on the body, wherein the barbs are all facing in a direction to the first and second end (col. 4, lines 58-59). Buncke further discloses the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (col. 8, lines 12-19). Buncke discloses the invention substantially as claimed except for disclosing **(1)** the barb

Art Unit: 3731

further has an underside base that is arcuate in the transverse direction to the longitudinal axis of the body and **(2)** the barb cut angle ranging from about 140 degrees to about 175 degrees, from about 152 degrees to about 165 degrees, and from about 152 degrees to about 163 degrees.

- a. As to point **(1)**, Morency discloses a similar barbed suture (Fig 1A) with a plurality of barbs (24) along an elongated suture body (22). Morency teaches the barbs may be rounded on both the topside of the barb (74) and underside of the barb (76) when the suture is used in delicate tissue prone to tearing ([0040] and Fig 1G). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Buncke such that the base at the underside of the barbs was arcuate to prevent tearing of delicate tissue.
- b. As to point **(2)**, Figures 15 and 16 of Buncke drawings show the barb 98, which created by cutting blade 92, wherein the blade has a sharp cutting edge, a base and an angle. Thus the barbs 98 of Buncke disclose the general condition of the barb cut angle  $\Theta$  on the suture. It would have been obvious to one having ordinary skill in the art at the time the invention was made to design the barb with the barb cut angle ranging from about 140 degrees to about 175 degrees, from about 152 degrees to about 165 degrees, and from about 152 degrees to about 163 degrees, since it has been held that where the general conditions of a claim are

disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

9. Referring to **claims 10-12**, Buncke discloses (see Figures 2 and 13) a barbed suture 84 having a elongate body having a longitudinal axis and barbs positioned on the body, wherein the barbs are all facing in a direction to the first and second end (col. 4, lines 58-59). Buncke discloses the invention substantially as claimed except for disclosing **(1)** the barb further has an underside base that is arcuate in the transverse direction to the longitudinal axis of the body and **(2)** the barb cut depth with a ratio of the barb cut depth to the suture diameter ranging from about 0.05 to about 0.6, from about 0.3 to about 0.55, and from about 0.4 to about 0.5.
  - a. As to point **(1)**, Morency discloses a similar barbed suture (Fig 1A) with a plurality of barbs (24) along an elongated suture body (22). Morency teaches the barbs may be rounded on both the topside of the barb (74) and underside of the barb (76) when the suture is used in delicate tissue prone to tearing ([0040] and Fig 1G). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Buncke such that the base at the underside of the barbs was arcuate to prevent tearing of delicate tissue.
  - b. As to point **(2)**, noting Buncke discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns and the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (col. 8, lines12-19). It would have been obvious to one

Art Unit: 3731

having ordinary skill in the art at the time the invention was made to design the barb with the barb cut depth with a ratio of the barb cut depth to the suture diameter ranging from about 0.05 to about 0.6, from about 0.3 to about 0.55, and from about 0.4 to about 0.5, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

10. Referring to **claims 19-22**, Buncke discloses (see Figures 2 and 13) a barbed suture 84 having a elongate body having a longitudinal axis and barbs positioned on the body, wherein the barbs are all facing in a direction to the first and second end (col. 4, lines 58-59). Buncke discloses the invention substantially as claimed except for disclosing **(1)** the barb further has an underside base that is arcuate in the transverse direction to the longitudinal axis of the body and **(2)** the barb cut length with a ratio of the barb cut length to the suture diameter ranging from about 0.2 to about 2, from about 0.4 to about 1.7, and from about 0.8 to about 1.5.

- a. As to point **(1)**, Morency discloses a similar barbed suture (Fig 1A) with a plurality of barbs (24) along an elongated suture body (22). Morency teaches the barbs may be rounded on both the topside of the barb (74) and underside of the barb (76) when the suture is used in delicate tissue prone to tearing ([0040] and Fig 1G). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was

Art Unit: 3731

made to modify the device of Buncke such that the base at the underside of the barbs was arcuate to prevent tearing of delicate tissue.

- b. As to point **(2)**, noting Buncke discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns and the distance between the barbs from about 100 micron to about 1 mm, depending, to a large extent, on the diameter of the suture material.(col. 8, lines12-19). Further, Figures 15 and 16 of Buncke drawings show the barb 98 having a barb cut length, thus the barbs 98 of Buncke disclose the general condition of the barb cut length. It would have been obvious to one having ordinary skill in the art at the time the invention was made to design the barb with the barb cut length with a ratio of the barb cut length to the suture diameter ranging from about 0.2 to about 2, from about 0.4 to about 1.7, and from about 0.8 to about 1.5, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.
11. Referring to **claims 28-30**, Buncke discloses (see Figures 2 and 13) a barbed suture 84 having a elongate body having a longitudinal axis and barbs positioned on the body, wherein the barbs are all facing in a direction to the first and second end (col. 4, lines 58-59). Buncke discloses the invention substantially as claimed except for disclosing **(1)** the barb further has an underside base that is arcuate in the transverse direction to the longitudinal axis of the body and **(2)** the barb cut



Art Unit: 3731

distance with a ratio of the barb cut distance to the suture diameter ranging from about 0.1 to about 6, from about 1 to about 3.5, and from about 1.5 to about 2.5.

- a. As to point **(1)**, Morency discloses a similar barbed suture (Fig 1A) with a plurality of barbs (24) along an elongated suture body (22). Morency teaches the barbs may be rounded on both the topside of the barb (74) and underside of the barb (76) when the suture is used in delicate tissue prone to tearing ([0040] and Fig 1G). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Buncke such that the base at the underside of the barbs was arcuate to prevent tearing of delicate tissue.
- b. As to point **(2)**, noting Buncke discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns and the distance between the barbs from about 100 micron to about 1 mm, depending, to a large extent, on the diameter of the suture material.(col. 8, lines12-19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to design the barb with the barb cut distance with a ratio of the barb cut distance to the suture diameter ranging from about 0.1 to about 6, from about 1 to about 3.5, and from about 1.5 to about 2.5, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Art Unit: 3731

12. Referring to **claim 58**, since claim 58 is the combination of claims 1, 10, 19 and 28, Examiner contends that based on the disclosure of Buncke, it would have been obvious to one of ordinary skill in art to modify the suture of Buncke to have all the parameter as claimed by the applicant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.
13. Referring to **claim 60**, since claim 60 is the combination of claims 1, 10, 19, 28, and a twist cut with a spirality angle  $\alpha$  ranging from about 5 degrees to about 25 degrees. Noting that Buncke also disclose the barbs can be positioned in a spiral pattern if desired (col. 9, lines 3-10), Examiner contends that based on the disclosure of Buncke, it would have been obvious to one of ordinary skill in art to modify the suture of Buncke to have all the parameter as claimed by the applicant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.
14. Referring to **claims 5-8, 14-17, 23-26, and 32-35**, Buncke discloses the suture can be nonabsorbable such as polyester or bioabsorbable material such as polymers and copolymers of glycolic and lactic acid (col. 1, lines 20-25).
15. Referring to **claims 9, 18, 27, and 36**, Buncke discloses the barbs can be on opposed sides of the suture, staggered, and they can be positioned in a spiral pattern if desired (col. 9, lines 3-10).

Art Unit: 3731

16. Referring to **claims 102-114**, Buncke discloses the suture 10 has about 100 to 500 microns in diameter (col. 4, lines 55-60), thus Buncke discloses the suture 10 having circular cross-section.
17. **Claims 4, 13, 22, 31 and 115-140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke (U.S. 5,931,855) and Morency et al. (US 2003/0149447) as applied to claims 1, 10, 19, and 28 above and further in view of Ruff (U.S. 5,342,376).**
18. Referring to **Claims 4, 13, 22, and 31**, Buncke/Morency discloses the invention substantially as claimed except for each set having a barb size different from the barb size of the other set. However, Ruff discloses the configuration of barbs 6 and the surface area of the barbs can vary depending upon the tissue in which the barbed suture is used (e.g. if the barbed suture is intended for use in fatty tissue, which is relatively soft, the barbs can be made longer to increase the holding ability in the soft tissue) (col. 4, lines 5-17 and col. 5, lines 2-6). It would have been obvious to one of ordinary skill in the art to design the barbed suture of Buncke/Morency to have at least two sets, wherein each set having a barb size different from the barb size of the other set for the purpose as disclosed by Ruff so that it too would have the same advantage.
19. Referring to **claims 115-140**, Buncke/Morency discloses the invention substantially as claimed except for the cross section of suture body has a non-circular cross section. However, Ruff discloses a non-circular cross section shape (e.g. rectangular or hexagonal cross section) increases the surface area of the

Art Unit: 3731

suture body and facilitates the formation of the multiple barbs on the suture body (col. 6, lines 18-28). It would have been obvious to one of ordinary skill in the art to incorporate the teaching of Ruff into the suture of Buncke/Morency so that it too would have the same advantage.

### ***Double Patenting***

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention

Art Unit: 3731

made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 1, 19, 28, and 58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 16, filed on 9/28/09, of copending Application No. 10/065280. Claim 16 discloses, a barbed suture comprising (a) an elongated body having a first end and a second end and a diameter and (b) a plurality of barbs projecting from the body, each barb facing in a direction and being adapted for resisting movement of the suture, when in tissue, in an opposite direction from the direction in which the barb faces, the suture comprising barbs with a configuration that includes I an arcuate base at the underside of the barbs, wherein: (I) the barbs have a multiple spiral disposition on the body, and (II) the barbs have a configuration selected from the group consisting of a barb cut angle  $\theta$  ranging from about 140 degrees to about 175 degrees, a barb cut depth with a ratio of the barb cut depth to the suture diameter ranging from about 0.05 to about 0.6, a barb cut length with a ratio of the barb cut length to the suture diameter ranging from about 0.2 to about 2, a barb cut distance with a ratio of the barb cut distance to the suture diameter ranging from about 0.1 to about 6, a corrugated barb underside, an arcuate barb base, at least two sets of barbs with each set having a barb size different from the barb size of the other set, and combinations thereof. As to claim 58 and 60, the difference between claim 58 of the present application and claim 16 of the copending

Art Unit: 3731

Application lies in the fact that claim 16 further discloses “(I) the barbs have a multiple spiral disposition on the body” and is thus much more specific. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially claimed the same invention.

22. Claims 1, 19, 28, and 60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 22, filed on 9/28/09, of copending Application No. 10/065280. Claim 22 discloses a barbed suture comprising (a) an elongated body having a first end, a second end and a diameter and (b) a plurality of barbs projecting from the body, each barb facing in a direction and being adapted for resisting movement of the suture, when in tissue, in an opposite direction from the direction in which the barb faces, the suture comprising barbs with a configuration that includes an arcuate base at the underside of the barbs, wherein: (I) the barbs have a disposition on the body comprising a multiple spiral disposition with a spirality angle  $\alpha$  ranging from about  $5^{\circ}$  to about  $25^{\circ}$  and (II) the barbs have a configuration comprising (i) a barb cut 0 angle ranging from about  $140^{\circ}$  to about  $175^{\circ}$  (ii) a barb cut depth with a ratio of the barb cut depth to the suture diameter ranging from about 0.05 to about 0.6, (iii) a barb cut length with a ratio of the barb cut length to the suture diameter ranging from about 0.02 to about 2, and (iv) a barb cut distance with a ratio of the barb cut distance to the suture diameter ranges from about 0.01 to about 6. As to claims 1, 19, 28, the difference between claims 1, 19, and 28 of the present application and claim 22 of the copending Application lies in the fact that claim 22 discloses much

Art Unit: 3731

more elements and is thus much more specific. Thus the more specific anticipates the broader.

23. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Genova et al. (U.S. 7,225,512) discloses (Figs. 1D-1F) a method of making barbed suture, wherein the barb includes an arcuate base that is transverse to the longitudinal axis of the suture body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./  
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
1/27/10